

REMARKS

This document is filed in reply to the Office Action dated September 13, 2005 ("Office Action").

Applicants have amended claims 1 and 3, each of which recites an ethanol concentration range narrower than the originally recited region. Support for the lower limits "50%" (in amended claim 1) and "65%" (in amended claim 3) can be found at page 6, line 5 of the specification and in original claim 1. On the other hand, support for the upper limit "75%" (in both amended claims 1 and 3) appears in the specification at, e.g., page 6, line 5. Claim 1, drawn to an extract, has also been amended to specify an activity of the extract. Support for the activity can be found in the specification, page 2, lines 15-19. Applicants have also amended claim 8, drawn to a composition containing a cytokine, to specify that the cytokine is active. Support for the term "active" appears in the specification, page 3, line 2. Finally, Applicants have cancelled claims 39-40 and added new claims 44 and 45. Support for new claims 44 and 45 appears in the specification, e.g., pages 5-6, carryover paragraph. No new matter has been introduced.

Upon entry of the above amendments, claims 1-38 and 41-45 will be pending. Among them, claims 20-38, and 41-43 have been withdrawn from further consideration for covering a non-elected invention. Claims 1-19, 44, and 45 are under examination. Reconsideration of this application is requested in view of the following remarks:

Rejection under 35 U.S.C. § 112, first paragraph

The Examiner rejected claims 1-19 for not complying with the written description requirement. It is the Examiner's position that "[t]he claim(s) contains subject matter which was not described in the specification in such a way to reasonably convey to one skilled in the relevant art that the inventor(s), at the time of the application was filed, had possession of the claimed invention." See the Office Action, page 2, last paragraph. To support her position, the Examiner refers to MPEP2136 and states:

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the application. These includes "the level of skill and knowledge in the art, partial structure, physical

and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials [and] would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." (see the Office Action, pages 2-4, carryover paragraph; emphasis added)

Applicants respectfully traverse. Independent claim 1 is discussed first. This claim, as amended, is drawn to an extract prepared from a tuber of a *Dioscorea* plant that (i) is soluble in water and insoluble in an aqueous solution containing 50%-75% ethanol between 0°C and 25°C and (ii) has an activity to enhance the proliferation of bone marrow or spleen cells. The specification teaches "the physical and/or chemical properties, functional characteristics, ... and the method of making the claimed invention." See, e.g., page 2, lines 9-19 (for physical and/or chemical properties and functional characteristics of the claimed extract) and pages 5-6, carryover paragraph (for a method of making the claimed invention.). In other words, the specification has "furnished ... [a combination] of [the] identifying characteristics that distinguish the claimed invention from other materials [and] would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species."

The Examiner further stated that "claims 1-19 are broad generic claims ... The specification lacks variety of extracts of *D. batatas* to reflect ... variance in the genus of 'extract' since the specification does not provide any other examples of extracts of *D. batatas* which provide for the claimed characteristics." See the Office Action, pages 4-5, carryover paragraph.

Applicants would like to point out that, contrary to the Examiner's statement, the specification "provide ... examples of extracts of *D. batatas* which provide for the claimed characteristics." For example, the specification discloses three extracts DsCE-I, DsCE-II, and DsCE-III, i.e., "variety of extracts of *D. batatas* to reflect ... variance in the genus of 'extract'." See, pages 5-6, carryover paragraph. In this connection, Applicants would like to point out that MPEP provides the following guidance as to meeting the written description requirement for a claimed genus:

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice ..., reduction to drawings ..., or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus ... (See MPEP 2163 IIA3(a) ii))

Here, the specification discloses three extracts DsCE-I, DsCE-II, and DsCE-III that were actually reduced to practice. Further as discussed above, the specification has furnished a number of identifying characteristics of the claimed extract. Thus, it is submitted that the specification is "sufficient to show the applicant was in possession of the claimed genus" and that independent claim 1 meets the written description requirement.

For the same reasons set forth above, independent claim 8 also meets the written description requirement. So are claims 2-7 and 9-19, as well as new claims 44-45, all of which depend from claim 1 or 8 and further specify the claimed extract.

Of note, new claims 44 and 45 are product-by-process claims. With regards to the written description requirement for such claims, MPEP 2163 IIA3(a)i) provides "[w]here the process has actually been used to produce the product, the written description requirement for a product-by-process claim is clearly satisfied." Applicants note that the specification teaches a process that "has actually been used to produce the product." See, e.g., page 5-6. carryover paragraph.¹ Accordingly, "the written description requirement for [] product-by-process claim[s] 44 and 45] is clearly satisfied" on this ground.

In view of the above remarks, Applicants submit that all of the claims being examined meet the written description requirement.

¹ Claims 44 and 45 cover extracts from a tuber of a *Dioscorea* prepared by a step-wise process including (i) extracting the tuber with water to obtain a water soluble fraction and then (ii) extracting the water soluble fraction, stepwise, with aqueous solutions containing various concentration of ethanol to obtain three ethanol-insoluble fractions. According to the specification, the extracts DsCE-I, DsCE-II, and DsCE-III were the three ethanol-insoluble fractions prepared by this process. See pages 5-6. carryover paragraph

Rejection under 35 U.S.C. § 102(b)

The Examiner rejected claims 1-19 for lack of novelty on two grounds. Applicants respectfully traverse each below.

I

The Examiner rejected claims 1-7 for being anticipated by Hikino *et al.* (Abstract of JP 61106516A; "Hikino"). See the Office Action, page 6, lines 12-13.

Original claim 1 is drawn to an extract from a tuber of a *Dioscorea* plant that is soluble in water and insoluble in an aqueous solution containing 65-90% ethanol between 0°C and 25°C. Hikino teaches preparing a polysaccharides-containing extract from a *Dioscorea* plant by extraction with water and then by precipitation with "4-6 fold of ... etOH." See the abstract, lines 9-11. In other words, the extract is insoluble in 80% to 85.7% etOH (i.e., ethanol).²

Applicants have amended independent claim 1 to replace "65-90%" with "50-75%." This claim, as amended, is drawn to a *Dioscorea* tuber extract that is soluble in water and insoluble in an aqueous solution containing 50-75% ethanol between 0°C and 25°C. As Hikino does not teach an extract that is insoluble in 50-75% ethanol, amended claim 1 is novel over Hikino. So are claims 2-6, as well as new claims 44 and 45, all of which depend from claim 1.

In addition, new claims 44-45 are drawn to *Dioscorea* tuber extracts prepared by a step-wise extraction process. Since Hikino does not teach this process, claims 44 and 45 are patentable over Hikino on this independent ground.³

II

The Examiner rejected claims 8-19 for being anticipated by a soup recipe by Ruiz *et al.* ("Ruiz"). See the Office Action, page 6, line 19 to page 7, line 2-6.

More specifically, independent claim 8, as amended, is drawn to a composition including an extract from a tuber of a *Dioscorea* plant and an active cytokine. Ruiz teaches a recipe for a

² "4-6 fold of ... etOH" refers to ratios of ethanol to water being 4:1 to 6:1. Accordingly, the concentration of ethanol is between 4/5 to 6/7, i.e., 80% to 85.7%.

³ Indeed, an extract prepared by Applicants' step-wise process contains compounds that do not exist in the Hikino extract. For example, it contains compounds that are insoluble in 75% ethanol and soluble in 80% ethanol. In contrast, the Hikino extract, which is precipitated directly from 80% to 85.7% ethanol, does not include compounds that are soluble in 80% ethanol.

Dominican soup. The soup is prepared by cooking yam and chicken, beef, mutton and pork in water for at least 45 minutes. According to the Examiner, the yam is the common name for *Dioscorea batatas* and chicken, beef, mutton and pork inherently contain cytokine. She then concluded that "it is deemed that the soup would contain a water extract of yam... and [an cytokine, such as] interleukin-2 (beef, pork, and chicken all inherently contain interleukin-2)." See the Office Action, page 7, lines 3- 6.

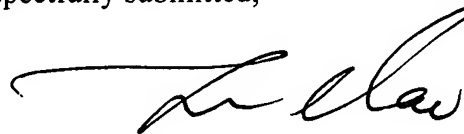
Applicants respectfully traverse. It is well known in the art that an cytokine, such as interleukin-2, is biological active signaling protein. It has a delicate three dimensional structure and is heat unstable. Under the cooking conditions described in Ruiz, it would be denatured and lose its three dimensional structure and biological activity. It follows that the soup cooked according to the Ruiz recipe does not contain any active cytokine, which is required in the composition of amended claim 8. Thus, claim 8, as amended, is novel over Ruiz. So are claims 9-19, all of which depend from claim 8.

CONCLUSION

Applicants submit that grounds for the objections and rejections asserted by the Examiner have been overcome, and that claims, as pending, define subject matter that is sufficiently described and novel. It is therefore submitted that allowance of this application is proper, and early favorable action is solicited. Enclosed is a \$225 check for the Petition for Extension of Time fee. Please apply any other charges to deposit account 06-1050, referencing the Attorney's Docket No. 08919-080001.

Respectfully submitted,

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